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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/786,361	07/26/2001	George M. Grass	109904-00015	6311

7590

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EXAMINER

BRUSCA, JOHN S

ART UNIT

PAPER NUMBER

1631

DATE MAILED: 08/12/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/786,361

Applicant(s)

GRASS ET AL.

Examiner

John S. Brusca

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 30 June 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-199 is/are pending in the application.
- 4a) Of the above claim(s) 54-79 and 122-136 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-53,80-121 and 137-199 is/are rejected.
- 7) ☒ Claim(s) 22 and 23 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 July 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 6/17/2001.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date: \_\_\_\_\_.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_.

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## DETAILED ACTION

### *Election/Restrictions*

1. Applicant's election without traverse of Group 1 in the reply filed on 30 June 2004 is acknowledged.
2. Claims 54-79 and 122-136 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 30 June 2004

### *Priority*

3. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119 (e) as follows:

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification or in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)). The specific reference to any prior nonprovisional application must include the relationship (i.e., continuation, divisional, or continuation-in-part) between the applications except when the reference is to a prior application of a CPA assigned the same application number.

It is apparent from International Publication No. WO 00/15178, the publication of International Application No. PCT/US99/21001, of which the instant application is a national stage filing under 35 U.S.C. §371, that the applicants intended to claim the benefit of a number of U.S. provisional applications. In order to perfect the claim for

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benefit of provisional applications, the applicants must amend the first sentence of the specification to refer to the claimed applications as required under 35 U.S.C. § 119(e).

***Information Disclosure Statement***

4. The Information Disclosure Statement filed 17 July 2001 does not contain a legible copy of each reference listed on the list of references. It is not known whether this is an error of the applicants or a scanning error by the Office. Consequently the missing references have been listed as not considered in the signed copy of the list of references attached to this Office action. If the applicants provide a legible copy of the missing references in response to this Office action, the references will be considered under 37 CFR 1.97(f), and a signed copy of the list of references indicating consideration of the missing references will be provided to the applicants without the necessity of the applicants filing a second Information Disclosure Statement.

5. The Information Disclosure Statement filed 17 July 2001 contains a list of references of 15 pages, however the list of references indicates that the list contains 16 pages. If the list of references is incomplete the applicants may provide a page 16 and associated legible copies of references for consideration as discussed above.

***Claim Objections***

6. Claims 22 and 23 are objected to because of the following informalities: The claims recite the term “mammal” and should be amended to recite “mammalian.”. Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 1, 80, and 81 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite for recitation in the preamble of the phrase “a test compound in an anatomical segment of a data source system” because it is not clear how a data source system can have an anatomical segment, and further because it is not clear if the anatomical segment is the same or different from the previously recited phrase “an anatomical segment of a target mammalian system.” The rejection would be overcome by amendment of the claim to recite “a test compound in a model of a second anatomical segment.”

Claim 1 is indefinite for recitation in part (b) of the term “segment” because it is not clear which segment the term refers to.

Claims 80 and 81 are indefinite for recitation in the preamble of the phrase “a test compound in an anatomical segment of a data source system” because it is not clear how a data source system can have an anatomical segment, and further because it is not clear if the anatomical segment is the same or different from the previously recited phrase “an anatomical segment of a target mammalian system.” The rejection would be overcome by amendment of the claim to recite “a test compound in a model of a second anatomical segment.”

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***Claim Rejections - 35 USC § 102***

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 1-53, 80-121, and 137-199 rejected under 35 U.S.C. 102(b) as being anticipated by Grass (reference BW in the Information Disclosure Statement filed 17 July 2001).

The claims are drawn to a method of using a pharmacokinetic model to predict a pharmacokinetic property of a compound in a second anatomical location by use of a pharmacokinetic property of a test compound in a first anatomical location. In some embodiments the claims are drawn to computers or programs that execute the method. In some embodiments the model uses in vitro data, log functions, programs and computers using if..then statements, models comprising absorption models in the gastrointestinal tract, differential equations, and models that comprise properties of two different species of animal or tissues or cells.

Grass et al. shows in the abstract and throughout pharmacokinetic models that predict behavior of compounds in animals. Grass shows use of in vitro models on page 204, models with log functions on page 205, computers and programs that execute the method on page 207, programs with if..then statements on page 207. models of

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absorption in the gastrointestinal tract on page 207 and throughout, models using differential equations on page 208, models that compare behavior of different species of animals on pages 209-211, and models that use behavior of tissue and in vitro cells on page 209-211. Grass shows in figures 19 and 20 that the models provide accurate predictions of absorption of two different compounds in the gastrointestinal tract.

### ***Double Patenting***

11. For the purpose of examination, the applicants intent to claim priority to U.S. Provisional Application No. 60/100224, filed 14 September 1998 discussed above has caused any possible rejections under 35 U.S.C. §102(e) over the U.S. Patents discussed below to be held in abeyance because such rejections would be overcome by the applicants perfecting their intended claim for priority.

12. An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would be obvious over, the reference claim(s). see, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985).

13. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed.

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Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

14. Claims 1-53, 80-86, 88-101, 104-121, 137-147, 149-163, and 165-199 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-82 of U.S. Patent No. 6,542,858. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of U.S. Patent No. 6,542,858 are drawn to species of the instant claims.

15. Claims 1-53, 80-86, 88-101, 104-121, 137-147, 149-163, and 165-199 are directed to an invention not patentably distinct from claims 1-82 of commonly assigned U. S. Patent No. 6,542,858. Specifically, claims of U.S. Patent No. 6,542,858 are drawn to species of the instant claims.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP § 2302). Commonly assigned U.S. Patent No. 6,542,858, discussed above, would form the



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basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications filed on or after November 29, 1999.

16. Claims 1, 2, 6, 7, 11-14, 19-23, 31, 32, 36, 44, 80-83, 90, 91, 93, 100, 106, 110, 111, 113, 114, 116, 137-139, 151, 153-160, 169, 176, 182, 184, 188, 192, 194, 196, 198, and 199 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 37-45, 61-66, 85-92, 109-120, 132, 133, 168, 179, 186-196, 231-242, 255-266, and 323 of U.S. Patent No. 6,647,358. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of U.S. Patent No. 6,647,358 are drawn to species of the instant claims.

17. Claims 1, 2, 6, 7, 11-14, 19-23, 31, 32, 36, 44, 80-83, 90, 91, 93, 100, 106, 110, 111, 113, 114, 116, 137-139, 151, 153-160, 169, 176, 182, 184, 188, 192, 194, 196, 198, and 199 are directed to an invention not patentably distinct from claims 37-45, 61-66, 85-

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92, 109-120, 132, 133, 168, 179, 186-196, 231-242, 255-266, and 323 of commonly assigned U.S. Patent No. 6,647,358. Specifically, the claims of U.S. Patent No. 6,647,358 are drawn to species of the instant claims.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP § 2302). Commonly assigned U.S. Patent No. 6,647,358, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications filed on or after November 29, 1999.

### ***Conclusion***

18. Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight

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(EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

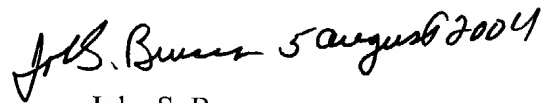
For all other customer support, please call the USPTO Call Center at (800) 786-9199.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John S. Brusca whose telephone number is (571) 272-0714. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-0722. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, reading "John S. Brusca 5 August 2004".

John S. Brusca

Primary Examiner

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jsb